

What is claimed is:

1. An isolated, breast cancer-associated polypeptide, said polypeptide comprising the characteristics of:

detectable at a higher concentration in serum of a human with breast cancer than in serum of a human without breast cancer; and

- (i) has a molecular weight of about 16 kD, and fails to bind an anion ion exchange resin in the presence of 50 mM sodium phosphate, pH 7.0,
- (ii) has a molecular weight of about 17 kD, about 30 kD, or about 35 kD, binds to an anion exchange resin in the presence of 50 mM sodium phosphate, pH 7.0, and elutes from the anion ion exchange resin in the presence of 25 mM sodium chloride in 50 mM sodium phosphate, pH 7.0,
- (iii) has a molecular weight of about 20 kD, about 24 kD, or about 35 kD, binds to an anion exchange resin in the presence of 50 mM sodium phosphate, pH 7.0, and elutes from the ion exchange resin in the presence of 50 mM sodium chloride in 50mM sodium phosphate, pH 7.0,
- (iv) has a molecular weight of about 35 kD, binds to an anion exchange resin in the presence of 50 mM sodium phosphate, pH 7, and elutes from the ion exchange resin in the presence of 50 mM sodium chloride in 50 mM sodium phosphate, pH 7.0,
- (v) has a molecular weight of about 18 kD or about 71 kD, binds to an anion exchange resin in the presence of 50 mM sodium phosphate, pH 7.0, and elutes from an ion exchange resin in the presence of 100 mM sodium chloride in 50 mM sodium phosphate, pH 7.0,
- (vi) has a molecular weight of about 12 kD, binds to an anion exchange resin in the presence of 50 mM sodium phosphate, pH 7.0, and elutes from an ion exchange resin in the presence of 150 mM sodium chloride in 50 mM sodium phosphate, pH 7.0,
- (vii) has a molecular weight of about 42 kD or about 56 kD, binds to an anion exchange resin in the presence of 50 mM sodium phosphate, pH 7.0, and elutes

from an ion exchange resin in the presence of 200 mM sodium chloride in 50 mM sodium phosphate, pH 7.0, or

(viii) has a molecular weight of about 35 kD, binds to an anion exchange resin in the presence of 50 mM sodium phosphate, pH 7.0, and elutes from an ion exchange resin in the presence of 400 mM sodium chloride in 50 mM sodium phosphate, pH 7.0.

2. The polypeptide of claim 1, wherein the polypeptide of clause (i), (iii) or (vii) is further characterized as having an affinity to a nickel SELDI chip.

3. The polypeptide of claim 1, wherein the polypeptide of clause (ii), (iv) or (v) is further characterized as having an affinity to a WCX-2 SELDI chip.

4. The polypeptide of claim 1, wherein the polypeptide of clause (vi) is further characterized as having an affinity to a SAX-2 SELDI chip.

5. The polypeptide of claim 1, wherein the polypeptide of clause (viii) is further characterized as having an affinity to a copper SELDI chip.

6. The polypeptide of claim 1, comprising the additional characteristic of being a non-immunoglobulin protein.

7. The polypeptide of claim 1, comprising the additional characteristic of being a non-albumin protein.

8. The polypeptide of claim 1, further comprising an epitope.

9. A method of diagnosing cancer in an individual comprising detecting in a sample isolated from the individual the presence of the polypeptide of claim 1, which if present is indicative of cancer in the individual.

10. The method of claim 9, wherein the cancer is breast cancer.

11. The method of claim 9, wherein the sample comprises breast tissue.

12. The method of claim 9, wherein the sample comprises a body fluid.
13. The method of claim 12, wherein the body fluid is selected from the group consisting of blood, serum, plasma, sweat, tears, urine, peritoneal fluid, lymph, vaginal secretions, semen, spinal fluid, ascitic fluid, saliva, sputum, and breast exudate.
14. The method of claim 13, wherein the body fluid is serum.

15. A method of diagnosing cancer in an individual, the method comprising the steps of:

- (a) contacting a sample from the individual with a binding moiety that binds specifically to a cancer-associated protein to produce a binding moiety-cancer-associated protein complex, wherein the binding moiety binds specifically to the polypeptide of claim 1; and
- (b) detecting the presence of the complex, which if present is indicative of the presence of cancer in the individual.

16. The method of claim 15, wherein the binding moiety is an antibody.
17. The method of claim 16, wherein the antibody is a monoclonal antibody.
18. The method of claim 16, wherein the antibody is a polyclonal antibody.
19. The method of claim 16, wherein the antibody is labeled with a detectable moiety.
20. The method of claim 19, wherein the detectable moiety comprises a member selected from the group consisting of a radioactive label, a hapten label, a fluorescent label, and an enzymatic label.
21. An isolated binding moiety that binds specifically the polypeptide of claim 1.
22. The binding moiety of claim 21, wherein the moiety is an antibody, an antigen-binding fragment thereof or a biosynthetic antibody binding site.
23. The binding moiety of claim 21, wherein the binding moiety is a monoclonal antibody.

24. A pharmaceutical composition comprising the binding moiety of claim 21 in a pharmaceutically-acceptable carrier.
25. A method of treating cancer in an individual, the method comprising administering to the individual a therapeutically-effective amount of the composition of claim 24.
26. The method of claim 25, wherein the cancer is breast cancer.
27. An isolated nucleic acid sequence encoding the protein of claim 1, or a sequence complementary thereto.
28. An isolated nucleic acid sequence comprising at least 15 nucleotides and capable of hybridizing under stringent hybridization conditions to the nucleic acid of claim 27.
29. An expression vector comprising the nucleic acid of claim 28.
30. A composition comprising the nucleic acid of claim 28 admixed with a pharmaceutically acceptable carrier.
31. A composition comprising the nucleic acid of claim 29 admixed with a pharmaceutically acceptable carrier.
32. A method of treating cancer in an individual, the method comprising introducing into cells of the individual the nucleic acid of claim 28.
33. The method of claim 32, wherein the cancer is breast cancer.
34. A method of detecting the presence of breast cancer in a human, the method comprising detecting the presence of a nucleic acid molecule in a tissue or body fluid sample of the human thereby to indicate the presence of breast cancer in the human, wherein the nucleic acid molecule comprises a nucleic acid sequence encoding at least a portion of the breast cancer-associated protein of claim 1 or a nucleic acid sequence capable of recognizing and being specifically bound by the breast cancer-associated protein.

35. The method of claim 34, wherein the method comprises the step of reacting the sample with a labeled hybridization probe capable of hybridizing specifically to the nucleic acid molecule.

36. A method of detecting the presence of cancer in an individual, the method comprising the steps of

exposing a sample from the individual under specific hybridization conditions to a nucleic acid probe capable of hybridizing specifically to a target nucleic acid encoding the polypeptide of claim 1; and

detecting the presence of a duplex comprising the nucleic acid probe,
the presence of the duplex being indicative of cancer in the individual.

37. The method of claim 36 further comprising the step of amplifying the target nucleic acid in the sample prior to exposing the sample to the nucleic acid probe.

38. The method of claim 36, wherein the cancer is breast cancer.

39. The method of claim 36, wherein the nucleic acid probe is labeled with a detectable moiety.

40. The method of claim 39, wherein the detectable moiety comprises a member selected from the group consisting of a radioactive label, a hapten label, a fluorescent label, and an enzymatic label.

41. A kit for detecting the presence of breast cancer or for evaluating the efficacy of a therapeutic treatment of a breast cancer, the kit comprising in combination:

a receptacle for receiving a tissue or body fluid sample from a mammal;

a binding moiety which binds specifically to the breast cancer-associated protein of claim

1;

and
a means for detecting the binding moiety bound to the breast cancer-associated protein;

a reference sample.

42. The kit of claim 41, wherein the reference sample is indicative of a normal breast sample.

43. A method of diagnosing cancer in a mammal, the method comprising the steps of:

(a) obtaining a sample isolated from the mammal; and

(b) detecting in the sample the presence of a protein characterized as comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1; SEQ ID NO: 2; SEQ ID NO: 3; SEQ ID NO: 4; SEQ ID NO: 5; SEQ ID NO:6; SEQ ID NO:7; SEQ ID NO:8; SEQ ID NO:9; SEQ ID NO:10; SEQ ID NO:11; SEQ ID NO:12; SEQ ID NO:13; SEQ ID NO:14; SEQ ID NO:15; SEQ ID NO:16; SEQ ID NO:17; SEQ ID NO:18; SEQ ID NO:19; SEQ ID NO:20; SEQ ID NO:21, SEQ ID NO:22; and SEQ ID NO:23, which if present is indicative of cancer in the mammal.

44. The method of claim 43, wherein the cancer is breast cancer.

45. The method of claim 44, wherein the sample comprises breast tissue.

46. The method of claim 43, wherein the sample comprises a body fluid.

47. The method of claim 46, wherein the body fluid is selected from the group consisting of blood, serum, plasma, sweat, tears, urine, peritoneal fluid, lymph, vaginal secretions, semen, spinal fluid, ascitic fluid, saliva, sputum, and breast exudate.

48. A method of diagnosing cancer in a mammal, the method comprising the steps of:

(a) contacting a sample derived from the mammal with a binding moiety that binds specifically to a cancer-associated protein to produce a binding moiety-cancer-associated protein complex, wherein said binding moiety binds specifically to a protein comprising an amino acid

sequence selected from the group consisting of SEQ ID NO: 5, SEQ ID NO:22, and SEQ ID NO:23; and

(b) detecting the presence of the complex, which if present is indicative of the presence of cancer in the mammal.

49. The method of claim 48, wherein the cancer is breast cancer.

50. The method of claim 48, wherein the binding moiety is selected from the group consisting of an antibody, an antibody fragment and a biosynthetic antibody binding site.

51. The method of claim 48, wherein the binding moiety is an antibody.

52. The method of claim 51, wherein the antibody is a monoclonal antibody.

53. The method of claim 50, wherein the binding moiety is labeled with a detectable moiety.

54. The method of claim 48, wherein the absence of a detectable amount of the protein is indicative of the absence of cancer.

55. The method of claim 48, further comprising the additional steps of:

(c) measuring an amount of the protein in the sample; and

(d) comparing the amount of the protein in the sample with a threshold value indicative of cancer in a mammal, wherein an amount of the protein in the sample greater than or equal to the threshold value is indicative of the presence of the cancer in the mammal.

56. A method of detecting the presence of cancer in a mammal, the method comprising: detecting the presence of a nucleic acid molecule in a tissue or body fluid sample of the mammal thereby to indicate the presence of cancer in the mammal, wherein the nucleic acid molecule comprises a nucleic acid sequence encoding the amino acid sequence set forth in SEQ ID NO:1; SEQ ID NO:2; SEQ ID NO:3; SEQ ID NO:4; SEQ ID NO:5; SEQ ID NO:6; SEQ ID NO:7; SEQ ID NO:8; SEQ ID NO:9; SEQ ID NO:10; SEQ ID NO:11; SEQ ID NO:12; SEQ ID NO:13; SEQ

ID NO:14; SEQ ID NO:15; SEQ ID NO:16; SEQ ID NO:17; SEQ ID NO:18; SEQ ID NO:19;
SEQ ID NO:20; SEQ ID NO:21, SEQ ID NO:22; or SEQ ID NO:23, or a fragment thereof.

57. The method of claim 56, wherein the detecting step comprises combining the sample with a labeled hybridization probe capable of hybridizing specifically to the nucleic acid molecule.

58. A method of detecting the presence of cancer in a mammal, the method comprising the steps of:

(a) combining a sample from the mammal under specific hybridization conditions with a nucleic acid probe capable of hybridizing specifically to a target nucleic acid encoding the amino acid sequence set forth in SEQ ID NO:1; SEQ ID NO:2; SEQ ID NO:3; SEQ ID NO:4; SEQ ID NO:5; SEQ ID NO:6; SEQ ID NO:7; SEQ ID NO:8; SEQ ID NO:9; SEQ ID NO:10; SEQ ID NO:11; SEQ ID NO:12; SEQ ID NO:13; SEQ ID NO:14; SEQ ID NO:15; SEQ ID NO:16; SEQ ID NO:17; SEQ ID NO:18; SEQ ID NO:19; SEQ ID NO:20; SEQ ID NO:21, SEQ ID NO:22; or SEQ ID NO:23; and

(b) detecting the presence of a duplex comprising the nucleic acid probe, the presence of the duplex being indicative of cancer in the mammal.

59. The method of claim 58, further comprising the step of amplifying the target nucleic acid in the sample prior to combining the sample with the nucleic acid probe.

60. The method of claim 58, wherein the cancer is breast cancer.

61. The method of claim 58, where the nucleic acid probe is labeled with a detectable moiety.

62. The method of claim 61, wherein the detectable moiety comprises a member selected from the group consisting of a radioactive label, a hapten label, a fluorescent label, and an enzymatic label.